



UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tian Wen, Liu Liu, Mingqi Lu, Jieshan Bai, Y. Joseph Mo

Application No.: 10/815,119 Filed Date: 03/31/2004

Confirmation No. 6566 Group: 1614 Examiner: Not Assigned

For: Prostaglandin compositions and methods for the treatment of vasospasm.

CERTIFICATE OF MAILING	
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on <u>10/20/2004</u>	<u>Lynn F. McMiller</u>
Date	Signature
<u>Lynn F McMiller</u>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
☐ a Statement under 37 CFR 1.97(e), as checked below, or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
☐ a Statement under 37 CFR 1.97(e), as checked below, and
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☐ Copies of the cited references are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (*list reference not enclosed*) are not enclosed as these references were entered in earlier application, U.S. Application No. [], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☒ If copies of references AA – AK, AA2 – AB2 would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☒ Listed references AL, AO, AP, AS, AU were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

- ☒ The "concise explanation" requirement (non-English references) for reference(s) AW under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☒ the enclosed English language abstract.

☐ Applicant requests that the following pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account No. 50-1935 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

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By 

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PTO-109 REPRODUCED INFORMATION DISCLOSURE CITATION IN APPLICATION October 20, 2004 (Use several sheets if necessary)				ATTORNEY DOCKET NO.		APPLICATION NO.	
				301888-3012-101		10/815,119	
				APPLICANT NexMed (Holdings), Inc.			
FILING DATE				GROUP ART UNIT			
03/31/2004				1614			
U.S. PATENT DOCUMENTS							
EXAM- -NER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,029,814	14 June 1977	Bundy	424	308	
	AB	4,212,987	15 July 1980	Axen	560	121	
	AC	4,820,732	11 Apr 1989	Shell, et al.	514	573	
	AD	4,955,878	11 Sept 1990	See, et al.	604	181	
	AE	4,980,378	25 Dec 1990	Wong, et al.	514	785	
	AF	5,082,866	21 Jan 1992	Wong, et al.	514	785	
	AG	5,252,605	12 Oct 1993	Ueno	514	573	
	AH	5,403,867	4 Apr 1995	Okumura, et al.	514	573	
	AI	6,046,244	4 Apr 2000	Buyuktimkin, et al.	514	785	
	AJ	6,118,020	12 Sept 2000	Buyuktimkin, et al.	560	155	
	AK	6,323,241	27 Nov 2001	Yeager, et al.	514	573	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	EP 0 292 643 A	30 Nov 1988	EP			
	AM	EP 0 503 887 A2	16 Sept 1992	EP			
	AN	WO 95/09590	13 Apr 1995	PCT			
	AO	WO 99/22714 A	14 May 1999	PCT			
	AP	CA 2 442 479 A	23 Nov 2000	CA			
	AQ						
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR	Buncke, H.J., "Microsurgery: Transplantation-Replantation", on-line edition, chapter 36, http://buncke.org/textbook.html , accessed December 13, 2002.					
	AS	Büyüktimkin, N., et al., "Chemical Means of Transdermal Drug Permeation Enhancement." In <i>Transdermal and Topical Drug Delivery Systems</i> , Tapash K. Ghosh et al., eds. (IL: Interpharm Press), pp.357-475 (1997)					
	AT	Cragg, A., et al., "Vessel wall arachidonate metabolism after angioplasty", <i>Am J Cardiol</i> 51:1441-45 (1983)					
EXAMINER				DATE CONSIDERED			

PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 301888-3012-101		APPLICATION NO. 10/815,119	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION October 20, 2004 (Indicate several sheets if necessary)				APPLICANT NexMed (Holdings), Inc.			
				FILING DATE 03/31/2004		GROUP ART UNIT 1614	
U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA 2	6,414,028	2 July 2002	Buyuktimkin, et al.	514	573	
	AB 2	6,489,207	3 Dec 2002	Furukawa, et al.	438	301	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU	Mizushima, Y., et al., "Prostaglandin E1 is more effective, when incorporated in lipid microspheres, for treatment of peripheral vascular diseases in man," JOURNAL OF PHARMACY AND PHARMACOLOGY 1983 vol. 35, no. 10, 1983, pages 666-667.					
	AV	Sakai, Y., et al., "Prostaglandin E2 regulates the expression of basic fibroblast growth factor messenger RNA in normal human fibroblasts," <i>Kobe J. Med. Sci.</i> 47:35-45 (2001).					
	AW	Slodicke, R., et al. "Die Anwendung von Prostaglandin E ₁ bei mikrovasculären Rekonstruktion der oberen Extremität nach Akuttraumen, (Using Prostaglandin E ₁ in microvascular reconstruction of the upper extremity after acute trauma)," <i>Unfallchirurg, Jan; 105(1): 14-8 (2002).</i> (English abstract on page 15).					
	AX	Smalling, Richard W. et al., "Infarct salvage with liposomal prostaglandin E-1 administered by intravenous bolus immediately before reperfusion in a canine infarction-reperfusion model," CIRCULATION, vol.92, no.4, 1995, pages 935-943.					
	AY	Zollikofer, C.L., et al., "Prostaglandins and angioplasty. An experimental study in canine arteries," <i>Radiology</i> , 149(3): 681-5 (1983).					
EXAMINER				DATE CONSIDERED			